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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

RANDY SMITH, Individually and On Behalf of All Others Similarly Situated, *Plaintiff*, v. ANTARES PHARMA, INC., ROBERT F. APPLE and FRED M. POWELL, *Defendants*.	Civil Action No.: 17-8945(MAS)(DEA) CLASS ACTION **JURY TRIAL DEMANDED** **CONSOLIDATED THIRD AMENDED CLASS ACTION COMPLAINT**

Lead Plaintiff Serghei Lungu ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his consolidated third amended class action complaint against Defendants, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through its attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Antares Pharma, Inc. ("Antares" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set

forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Antares common stock between December 21, 2016 and October 12, 2017, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Antares develops, manufactures and commercializes therapeutic products using its drug delivery systems. Its subcutaneous injection technology platforms include the VIBEX disposable pressure-assisted auto injector system suitable for branded and generic injectable drugs in unit dose containers, reusable needle-free spring-action injector devices, and disposable multi-use pen injectors for use with cartridges. The Company distributes its needle-free injector systems in various countries. Antares also conducts research and development with transdermal gel products and has several products in clinical evaluation with partners.

3. Founded in 1979, the Company is headquartered in Ewing Township, New Jersey. Antares's common stock trades on the NASDAQ Capital Market ("NASDAQ") under the ticker symbol "ATRS."

4. At all relevant times, Antares's product Xyosted (known until May 2017 as QuickShot Testosterone, or "QST") was the Company's lead product candidate. Xyosted is an auto injector product designed for testosterone replacement therapy ("TRT").

5. While injectable testosterone has been commercially available in the U.S. for almost 70 years, Antares's auto injector was promoted as a painless and efficient injection.

6. Antares announced its submission of a New Drug Application ("NDA") for Xyosted to the U.S. Food and Drug Administration ("FDA") on December 21, 2016. Shortly thereafter, Defendants announced that the target date for completion of the FDA's review of the Xyosted NDA would be October 20, 2017.

7. Throughout the Class Period, Defendants made misrepresented and outright omitted key details in their communications with investors regarding the Xyosted NDA as follows:

- Defendants' public filings referred to a random list of "adverse events," which were vaguely quantified as having incidences "equal to or above five percent." But one of these adverse events, hypertension (or high blood pressure) showed a ***more than 200%*** increase when compared to TRT alternatives.
- Defendants disclosed a single completed suicide in Xyosted's clinical development, but failed to tell investors that there was an attempted suicide as well. This was a critical omission because even the lone reported suicide – the first reported suicide in a clinical study of TRT – created immense risk for the Xyosted NDA. The FDA weighed the attempted suicide with as much seriousness as it did the completed attempt.
- Defendants likewise disclosed a single instance of patient depression, but again failed to mention a second occurrence. As Defendants themselves acknowledged to the FDA, suicide can be an adverse outcome of depression, and therefore suicide events during QST-13-003 were possibly related to Xyosted.

8. Defendants' conduct is particularly galling given that they were specifically told by the FDA in ***November 2016*** – prior to the start of the Class Period – that that suicide,

depression, and hypertension would be review issues in the FDA's evaluation of the Xyosted NDA, and that the adverse events might lead to the exact type of labeled warning that was ultimately mandated for Xyosted.

9. The adverse effects were also of heightened significance because Antares did not include a control arm in its clinical studies of Xyosted, instead opting for a risky regulatory shortcut in a bid to attain rapid profitability. The shortcut allowed Defendants to rely on past safety research used by other drug companies gain approval for their TRTs. This meant that the company needed to match, but not exceed, the incidence of hypertension and suicide in those comparable trials (which Xyosted failed to do).

10. Defendants rushed to perform a quick extension study in an attempt to influence the FDA – despite knowing of the adverse events described above, as well as the FDA's then-current requirement that new drug sponsors conduct blood pressure studies. Indeed, Defendants attempted an end-run around this requirement by simply excluding patients with high blood pressure from the extension study altogether.

11. While the threat to the Xyosted NDA posed by the incidents of increased blood pressure and suicidality were raised and discussed internally at Antares, increases in hypertension and additional suicide/depression events were not disclosed to investors in the announcement of final study results for Xyosted's pivotal trial, nor indeed at any time prior to the FDA's initial rejection of the Xyosted NDA.

12. During the Class Period, Defendants equated FDA approval with profitability, even though the increase in hypertension associated with Xyosted risked rejection of the NDA, or black box labeling that could have a negative impact on doctors prescribing Xyosted, and otherwise negatively impact the Company's financial position.

13. Because the FDA is statutorily-prohibited from discussing an active NDA outside of an advisory committee – which did not occur here, Defendants were the primary source that investors relied upon concerning the Xyosted NDA.

14. After the market had closed on October 12, 2017, Antares revealed to investors that the Company had received a letter from the FDA on October 11, 2017, that "identified deficiencies that preclude the continuation of the discussion of labeling and post marketing requirements/commitments" for Xyosted. (This was followed up a week later with a Complete Response Letter ("CRL") from the FDA rejecting "the NDA in its present form" as the FDA was concerned that Xyosted "could cause a clinically meaningful increase in blood pressure" as well as "the occurrence of depression and suicidality.")

15. On the revelation of the October 11, 2017 FDA letter, Antares common stock fell 37.80%, or $1.41 per share, and closed at $2.32 per share on October 13, 2017.

16. Just days earlier, on October 9, 2017, Antares's Chairman of the Board, Leonard S. Jacob, sold hundreds of thousands of shares from his personal portfolio, reaping a windfall of nearly $1 million.

17. Antares eventually resubmitted the NDA for Xyosted, and on October 1, 2018, the Company announced that the FDA had approved the drug, but required a black box warning describing the increased blood pressure that could lead to major adverse cardiovascular events. as well as a separate section on the "Risk of Depression and Suicide" under "Warnings and Precautions." Another concealed risk hidden by Defendants' non-disclosures had now materialized.

18. On the heels of the revelation of approval with the requirement of a black box warning and risk of depression and suicide, Antares common stock fell 3%, or $0.10 per share, and closed at $3.16 per share on October 1, 2018.

19. Both the CRL and the boxed warning were directly attributable to the same hypertension, suicide, and depression data that Defendants hid from investors during the Class Period.

20. Upon the disclosures and materialization of the risks of Defendants' wrongful acts and omissions, and the accompanying precipitous decline in the market value of the Company's securities, Plaintiff and other Class members suffered significant losses and damages.

JURISDICTION AND VENUE

21. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and Section 27 of the Exchange Act.

23. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). Antares's principal executive offices are located within this Judicial District.

24. In connection with the acts, conduct and other wrongs alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

25. Plaintiff acquired Antares securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged disclosures and/or materialization of the risks.

26. Defendant Antares is incorporated in Delaware, with principal executive offices located at 100 Princeton South, Suite 300, Ewing, New Jersey 08628. Antares's shares trade on the NASDAQ under the ticker symbol "ATRS."

27. Defendant Robert F. Apple ("Apple") has served at all relevant times as the Company's Chief Executive Officer ("CEO"), President and Director.

28. Defendant Fred M. Powell ("Powell") has served at all relevant times as the Company's Chief Financial Officer ("CFO") and Senior Vice President.

29. Defendant Leonard S. Jacob ("Jacob") has served at all relevant times as the Company's Chairman of the Board ("COB"). On October 9, 2017, three days before the risks concealed by Defendants began to materialize, COB Jacob sold 200,000 shares of Antares stock at $4.0521 and an additional 30,000 shares of Antares stock at $4.05 for a total of $931,920.

30. The defendants referenced above in ¶¶27-29 are sometimes referred to herein as the "Individual Defendants."

SUBSTANTIVE ALLEGATIONS

Background

The New Drug Approval Process

a. General Protocols

31. In the United States, pharmaceutical development and marketing is regulated by the FDA. Any company seeking to market a pharmaceutical product in the United States (in industry parlance, a "sponsor") must obtain prior approval from the FDA, and that the approval

has to be based upon substantial scientific evidence demonstrating that the product is safe and effective for its intended use in humans.

32. Prior to conducting any clinical research in humans, a sponsor must file an Investigational New Drug ("IND") application with the FDA.

33. The sponsor, and not the FDA, is responsible for determining the design of clinical trials and the protocols for each trial.

34. The success or failure of a clinical trial is measured principally by whether the trial meets pre-specified endpoints, and by the statistical significance of its results.

35. A sponsor generally conducts clinical trials in three phases. These phases, which are codified in FDA regulations, *see* 21 C.F.R. § 312.21., are as follows:

36. Phase 1. Phase 1 studies "are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." *Id.*

37. Phase 2. Phase 2 studies are "typically well controlled" studies "conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug." *Id.*

38. Phase 3. Phase 3 studies are expanded studies "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects." *Id.*

39. When a sponsor believes it has conducted sufficient well-controlled clinical trials, and believes that those trials demonstrate substantial evidence of efficacy and safety consistent with the Food, Drug and Cosmetic Act, the sponsor may prepare and file a New Drug Application ("NDA")[1] with the FDA seeking approval for the marketing of the subject drug. The FDA never approves a drug for general use and NDAs, accordingly, do not seek approval for general use. Instead, NDAs seek and the FDA, when presented with scientific evidence meeting the statutory criteria for approval, grants approval for the sponsor to market the subject drug in a specific dose for the treatment of a specific condition or "indication," manufactured pursuant to a specific method, and packaged with a specific label.

40. Within 60 days of receiving an NDA, the FDA will accept the NDA for filing if it believes the NDA is sufficiently complete to permit a substantive review of the information contained within the NDA.

41. The filing of an NDA triggers review deadlines specified in the Prescription Drug User Fee Act ("PDUFA"). The date by which the FDA must issue its response is frequently referred to as a drug's "PDUFA date."

42. Prior to the PDUFA date, the FDA's Center for Drug Evaluation & Research may (or may not) convene an advisory committee to provide it with technical advice, enhance its decision-making process, and provide a forum for public discussion of controversial issues.

43. During the NDA review process, an advisory committee is the only forum in which the public can legally be advised by the FDA of (i) the FDA's position, and (ii) the FDA's interactions with the sponsor regarding the drug candidate. Except in advisory committee

[1] Or, in the case of a biologic molecule or tissue, a Biologics Licensing Application ("BLA"). This case involves Xyosted, a pharmaceutical drug candidate. Accordingly, it does not involve a BLA.

briefing documents and during the advisory committee hearing, FDA secrecy regulations strictly prohibit the agency from disclosing information regarding pending NDAs. As a result, without an advisory committee, the FDA may not publicly refute a sponsor's misrepresentations regarding clinical trials, protocols, or the sponsor's interactions with the FDA. *See* 21 C.F.R. § 314.430.

44. If the FDA finds that the NDA fails to provide the substantial evidence of efficacy and safety required by statute, or has other material shortcomings which prevent approval, the FDA will send the sponsor a Complete Response Letter, or "CRL," identifying the reasons why the application was not approved.

45. CRLs are never made public by the FDA at the time they are issued (although the agency will sometimes release the CRLs in redacted form years later, after the drug candidate is approved or officially abandoned).

46. Accordingly, investors must rely on sponsor companies to provide accurate information regarding CRLs, which can have a devastating effect on a small company's share value.

47. A sponsor may continue to pursue approval of a drug candidate after receiving a CRL by resubmitting its NDA within a specified time period, as extended. An NDA resubmission is also called the sponsor's "complete response" to the CRL.

b. <u>The FDA 505(b)(2) Regulatory Shortcut</u>

48. Established under the Hatch-Waxman Amendments of 1984 to the Federal Food, Drug, and Cosmetic Act, the FDA 505(b)(2) Regulatory Pathway expressly permits the FDA to rely, for approval of NDAs, on data not developed by the applicant.

49. The Hatch-Waxman Amendments were intended to balance the competing interests in the pharmaceutical industry of inducing pioneering research and development of new drugs, and to enable competitors to bring low-cost, generic copies of those drugs to market.

50. The 505(b)(2) shortcut to approval was intended to motivate innovation without creating duplicate work on what is already known about a drug.

51. Through a 505(b)(2) NDA an applicant may receive approval for marketing a new drug, even though one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted." As such, a sponsor of a drug submitted under 505(b)(2) NDA may rely not only on its own studies, but also on published reports of studies (whether or not it has a right of reference), the FDA's own findings of safety and efficacy on other previously FDA-approved drugs, or some combination of these. Thus, by relying on the information already known about the previously approved FDA drug, it reduces the time to bring a product to the market and, in theory, increases competition.

52. Although a 505(b)(2) NDA must directly demonstrate that the proposed drug product is safe and effective (as required by a full NDA), a 505(b)(2) applicant may – as noted above – rely on clinical studies that were previously submitted to the FDA in support of another drug that were not conducted or licensed by the 505(b)(2) applicant. The drug for which the borrowed studies were conducted is referred to as the "Reference Listed Drug" ("RLD"). A 505(b)(2) applicant may proffer these RLD-related clinical studies to satisfy the applicant's burden, in part or in its entirety, of proving the drug's safety and effectiveness.

53. Also as noted above, a 505(b)(2) NDA may also include the applicant's own research supporting the basic safety and efficacy of the drug in addition to the research studies

related to the RLD, or it may rely entirely on the studies conducted by outside entities on the RLD. Regardless, a 505(b)(2) applicant must submit information to the FDA that bears upon the safety and efficacy of its drug product in light of the difference between the pioneer drug product and the applicant's modification of that drug product. Thus, a 505(b)(2) applicant can "bridge" the safety and efficacy of its proposed product to the RLD by proffering studies of the relative bioavailability and bioequivalence of the approved RLD and the proposed drug candidate. Hence, this process is known as "bridging."

54. Perhaps the greatest advantage of the 505(b)(2) application is that it is expedited – allowing sponsors to avoid conducting time-consuming and expensive new clinical trials by using previously published studies and prior FDA findings on safety and effectiveness on similar approved drugs. Sponsors of 505(b)(2)s are required to pay a user fee under the PDUFA, but in return they get a PDUFA review clock of about 10 months for a standard application and six months for a priority application.[2]

55. While the 505(b)(2) regulatory pathway allows reduced cost, risk, and time to approval because of the ability to utilize existing data, the publicly available data must be of a standard acceptable to the FDA, with an appropriate bridging strategy and justification to a standard acceptable to the FDA.

56. A 2018 analysis of publicly-reported CRLs issued by the FDA from January 1, 2017 until May 30, 2018 found that small companies received most of the CRLs issued during this period, of those that were publicly reported.[3]

[2] Historically, drugs under the FDA's standard 505(b)(1) pathway take as long as fifteen years and a nine-figure investment to work their way through the system.

[3] *See* https://camargopharma.com/2018/06/complete-response-letters-crls/

57. Further analysis demonstrated that 80% of the CRLs issued for drug products were to companies planning to utilize the 505(b)(2) regulatory pathway for US FDA approval, and that all of the 80% were small companies.[4]

Background on TRTs

58. Testosterone levels decline naturally in men as they age over decades. Certain conditions can also lead to abnormally low testosterone levels.

59. Over time, the testicular "machinery" that makes testosterone gradually becomes less effective, and testosterone levels start to fall, by about 1% a year, beginning in the 40s. As men get into their 50s, 60s, and beyond, they may start to have signs and symptoms of low testosterone such as lower sex drive and sense of vitality, erectile dysfunction, decreased energy, reduced muscle mass and bone density, and anemia. Taken together, these signs and symptoms are often called hypogonadism ("hypo" meaning low functioning and "gonadism" referring to the testicles). Researchers estimate that the condition affects anywhere from two to six million men in the United States. Hypogonadism is also commonly referred to as "low testosterone" or, even more colloquially, "Low T."

60. Testosterone as a synthesized steroid was first approved by the FDA in 1939 as the first synthetic steroid.

61. Testosterone enanthate was introduced on the market in the 1950s by Squibb (later Bristol-Myers Squibb). *Enanthate* refers to an organic compound that is introduced to aid in extending release of the testosterone in the blood stream when injected.

62. Due to slow release properties, testosterone enanthate retains relatively high viscous properties, which can make injections difficult and painful. In addition, testosterone

[4] *Id.*

enanthate injections have traditionally been administered in medical offices, necessitating an in-person patient visit every two to four weeks.

63. Aside from injections, other TRTs are available, including topical patches and gels. However, patch therapies have experienced extremely high rates of skin irritation, while a significant number of patients have proven unable to absorb gel-based therapies. Additionally, gels carry a high risk of transfer of the drug to spouses and children. Pills are also available for testosterone supplementation, but their use is strongly discouraged because the pill therapies currently available in the United States are known to cause significant liver toxicity.

64. The standard target in TRT is the mid to upper range of normal, which usually means around 500 to 600 ng/dl (nanograms per decilitre). A reading of less than 300 ng/dl is considered indicative of low testosterone in the blood.

65. An auto injector is a device for injecting oneself with a single, preloaded dose of a drug that typically consists of a spring-loaded syringe activated when the device is pushed firmly against the body. By simply pressing a button, the syringe needle is automatically inserted and the drug is delivered. By design, auto injectors are easy to use and are intended for self-administration by patients, or administration by untrained personnel. Auto injectors were initially designed to overcome the hesitation associated with self-administration of the needle-based drug delivery device.

66. To administer testosterone enanthate subcutaneously with an auto injector, a highly advanced device is required.

67. The development of the auto injector for testosterone enanthate was intended to improve upon other forms of TRTs like gels and conventional injections, thereby tapping into a $2.3 billion TRT market in the US alone.

Antares Seeks FDA Approval For QST/Xyosted

68. In December 2012, Antares conducted a pre-IND meeting with the FDA as part of preparing to initiate clinical development of QST.

69. In 2013 Antares was granted a patent for an auto-injector, Vibex QuickShot ("QuickShot"), to be utilized in the subcutaneously administration of QST.

70. In July 2014, Antares began a multi-center, Phase 3 clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot auto injector in testosterone deficient adult males. QST-13-003 is also referred to herein as Xyosted's "pivotal trial."

71. Pursuant to Section 801 of the Food and Drug Administration Amendments Act of 2007, which requires the submission of basic results for certain clinical trials, generally no later than one year after their completion date, the sponsor or principal investigator of a clinical study provides information to the National Library of Medicine ("NLM") at the National Institutes of Health ("NIH"), which is then posted to the ClinicalTrials.gov website. Studies are generally submitted to ClinicalTrials.gov when they begin, and the information on the site is updated throughout the study.

72. Defendants were enabled to begin reporting on QST-13-003 to the NLM/NIH on June 6, 2014, though no study results were publicly disclosed until after the end of the Class Period.

73. In Antares's QST-13-003 study, 150 adult males with low testosterone and testosterone blood levels less than 300 ng/dL (nanograms per decilitre) received a starting dose of 75 mg of QST once weekly for six weeks. Blinded adjustments to dose were made when necessary at week seven based upon the week six pre-dose blood level, and full pharmacokinetic

profiles were obtained during the twelfth week of treatment. The primary endpoint was the percentage of patients achieving an average serum total testosterone concentration of 300 to 1,100 ng/dL.

74. On November 3, 2014, Antares announced that the last patient had been enrolled in QST-13-003.

75. On February 25, 2015, Antares announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company's QST-13-003 clinical study.

76. FDA reports confirm that psychiatric adverse events observed in the QST clinical studies included one case of completed suicide, one case of suicide attempt, and two cases of depression.[5]

77. The FDA reports refer collectively to the suicide-related events as attempted and completed "suicides," plural, or, alternately "suicide attempts."

78. Between the initiation of QST-13-003 in July 2014 and the reporting of top-line results in February 2015, Antares received written recommendations from the FDA related to its clinical development program for QST. The recommendations received were in response to various clinical, chemistry, manufacturing and controls and user study submissions that Antares made through November 2014.

79. According to Antares, the FDA recommended that the Company create a larger safety database, including approximately 350 subjects exposed to QST with approximately 200 subjects exposed for six months and approximately 100 subjects exposed for a year.

[5] The FDA reports referred to herein were not publicly released until 2019, but the FDA's specific concerns in the reports regarding increased hypertension, suicides and depression found in the Xyosted studies were reported to Antares by the FDA at least as early as November 2016 *via* responses to a series of clinical questions proffered by the Company.

80. Between June and November 2015, Antares finalized and submitted the protocol for, and enrolled patients in a second Phase 3 study of QST (QST-15-005) pursuant to the FDA's recommendations. The dose-blinded, multiple-dose, concentration-controlled, 26-week QST-15-005 study included a screening phase, a titration phase and a treatment phase for evaluation of safety and tolerability, including laboratory assessments, adverse events and injection site assessment.

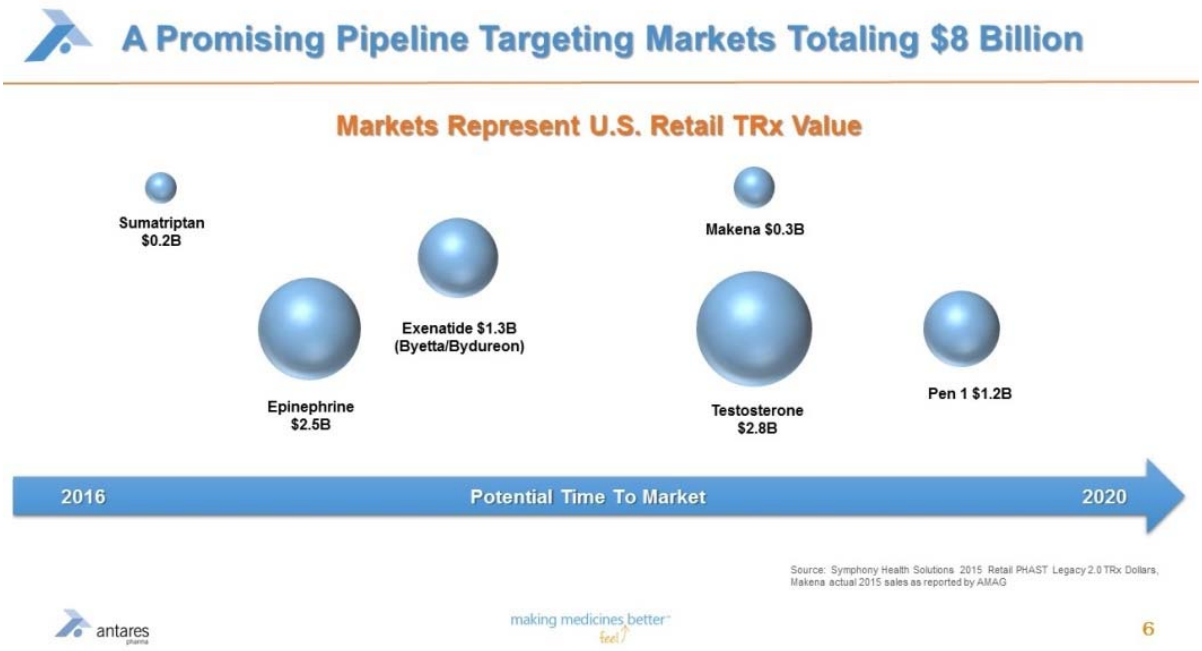
81. Defendants begin reporting on QST-15-005 to the NIH on July 20, 2015, though no study results were publicly disclosed until after the end of the Class Period.

82. By this point, Defendants were aware that their clinical studies showed a problem with hypertension. This is confirmed by Defendants' exclusion of patients with baseline hypertension from participation in QST-15-005. As the FDA noted in a Clinical Review dated September 25, 2017:

> Of significant relevance to this issue is that the protocol for Study QST 15-005 specifically called for a baseline normotensive study population , serving to limit the "worst case" as it pertains to the maximum possible effect of QST TE on blood pressure increases in the key subpopulation of hypertensive patients, who are an intrinsic part of the … target patient population.

83. Despite the patient exclusion, an FDA report refers to the potential for Xyosted to raise average systolic blood pressure (SBP) by approximately 4 mm Hg, a clinically meaningful amount. Specifically, ambulatory blood pressure measurements in QST-15-005 showed that treatment with Xyosted was associated with mean systolic/diastolic BP increases of 4/2 mm Hg.

84. By 2015, Antares valued QST as the most lucrative individual component its development pipeline, at $2.8 billion:



85. In the Company's annual report filed with the SEC on March 8, 2016 on Form 10-K, Antares reported on the purported complete results of QST-13-003. Among other things, the Company announced that "there has been one reported death, which was caused by suicide, and …. [t]here was one serious adverse event ("SAE") of hospitalization for worsening depression in a patient with a history of depression." However, the 2016 10-K did not mention hypertension, and the full QST-13-003 study results that referenced hypertension rates would not be publicly-disclosed until December 12, 2017, more than two months after the end of the Class Period.

86. On April 12, 2016, the Company announced that it faced potential delisting by the NASDAQ owing to the fact that for 30 consecutive trading days preceding the date of the Notice of Delisting, the bid price of the Company's common stock had closed below the $1.00 per share minimum required for continued listing on The NASDAQ Capital Market pursuant to NASDAQ Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Rule").

87. By June 2016, the last patient had completed treatment under QST-15-005, and on September 22, 2016 Antares announced the results of the study via a press release. Among the

safety population – comprised of 133 patients – it was claimed that the most common adverse reactions (incidence ≥5%) were increased hematocrit, upper respiratory tract infection and injection site ecchymosis.

88. However, the September 22, 2016 press release egregiously omitted to tell investors of the 213% increase in hypertension found in the tests, and the full QST-15-005 study results would not be publicly disclosed until March 29, 2018, more than five months after the end of the Class Period.

89. On October 31, 2016, Antares abruptly cancelled its upcoming "pre-NDA" meeting with the FDA, scheduled for November 2, 2016. The pre-NDA meeting has been described as "a critical meeting between the sponsor and FDA to ensure the submission of a well-organized and readily reviewable NDA", including in regard to "safety and efficacy."[6]

90. On November 9, 2016, during an earnings call announcing Antares's results for the third quarter of 2016, Defendant Apple did not mention the pre-NDA meeting cancelation, disclosing only that the Company had "completed the clinical portion of the phase 3 work" with respect to QST and was "targeting a year-end [NDA] submission."

91. On November 28, 2016, the FDA wrote to Antares, enclosing final responses to a series of clinical questions proffered by the Company. In the course of its answers, the FDA informed Defendants that:

- "The observed increases in blood pressure in studies QST-13-003 and QST-15-005 will a review issue. These increases appear potentially clinically significant";
- "Adverse events of depression and suicide, and cardiovascular and cerebrovascular AEs, will be review issues";

[6] *See* http://regardd.org/drugs/drug-development/meetings

- "Reports of increased BP, cardiovascular and cerebrovascular adverse events, and depression/suicide may prompt the need for an [advisory committee]"; and
- "[A]dverse events from the safety database in from the phase 3 study may be included in labeling[.]"

92. Despite the FDA's stated concerns, Defendants press forward and filed the NDA on December 20, 2016.

93. On the Company's May 9, 2017 earnings call, Defendant Apple announced that Defendants had selected the name "Xyosted" for the Company's flagship product. He explained that "[t]he first two letters, X-Y, represents the male chromosome" while "[t]he last four letters S-T-E-D is intended to both reflect the name of our Phase 3 clinical trial, which was named STEADY and to convey the idea that weekly injections of our subcutaneous testosterone was associated with steady physiologically normal levels of testosterone as shown by our PK data collected from our studies."

94. To finance the anticipated launch of Xyosted, management announced in June 2017 that it had secured financing for up to $35 million, which carried interest-only payments for the following 24 months, after which, it was anticipated, the Company would be profitable.

95. Xyosted was developed under the 505(b)(2) regulatory pathway – discussed above – in which clinical trials had to show that Xyosted does not (or only rarely) result in blood levels of testosterone levels above an upper, or below a lower, bound during the course of therapy. These levels have been established by the FDA based on experience with numerous other testosterone formulations. As there was no control arm in the QST clinical trials,[7] the

[7] In a clinical trial, the phrase "control arm" refers to a group of participants that is not given the experimental intervention being studied (in this case, QST). The control arm can receive an intervention that is considered effective (the standard), a placebo, or no intervention. Outcomes

comparison between Xyosted, on the one hand, and other TRT drugs, on the other hand, would prove highly relevant with respect to the Xyosted NDA.

96. For its RLD, Antares relied primarily on Delatestryl, an injectable drug approved in 1953.

97. Unbeknownst to investors throughout the Class Period, but known at all relevant times within the Company, the incipient Xyosted NDA was facing serious risks in regard to (a) the clinically meaningful increase noted in blood pressure (*i.e.*, hypertension); and (b) the instance of suicidality/depression.

(a) Hypertension

98. As noted by the healthcare investment research site *Healthonym* following Antares's receipt of the CRL, the QST clinical studies showed a clear tendency towards a high risk of hypertension.

99. In particular, ***12.7%*** (19 cases; n = 150) of individuals in QST-13-003 and 2.26% of individuals (3 cases; n = 133) in QST-15-005 experienced hypertension; 7.77% between the two trials. This is about 10,161 cases of hypertension per 100,000 patient years. By comparison, among all Phase 3 trial data collected for 6 different TRTs approved in the last ten years, 81 or 4.05% of individuals experienced such an adverse event, which works out to approximately 3,564 cases of hypertension per 100,000 patient years among such trials.

100. For European clinical trials and post-marketing studies of TRTs, the risk of hypertension is even lower, at 1.88%.

101. As the FDA explained in its Summary Review of the Xyosted NDA:

Increases in blood pressure (BP) were observed in some patients in both Phase 3

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in the control arm are compared with those in the experimental arm to determine any differences, for example, in safety and effectiveness.

> studies. In the 6-month study QST 15-005, Xyosted increased systolic BP (SBP) within the first 12 weeks of treatment by an average of 4 mmHg based on ambulatory blood pressure monitoring (ABPM) measurements. In the 1-year study QST 13-003, Xyosted increased SBP from baseline also by an average of 4 mmHg based on BP cuff measurements - and 10% of Xyosted-treated patients were either started on antihypertensive (anti-HTN) medications or required changes to their existing anti-HTN medication regimen.

102. Insiders at Antares knew of the elevated blood pressure risk, yet consciously sought to downplay its significance instead of disclosing the direct link between QST and elevated blood pressure that the FDA would ultimately force the Company to acknowledge.

(b) Suicidality/Depression

103. The risk of suicide with Xyosted was far greater than with any other currently marketed TRT.

104. As explained in the *Healthonym* article, the most recent FDA approval of a drug, not intended for the treatment of psychiatric illness, which posed a unique safety signal with respect to suicide, above and beyond its competitors, involved a candidate with a suicide risk of 0.10% (or equal to 58 suicides per 100,000 patient years) in comparison to Xyosted's reported 0.27% (or 447 cases of suicide per 100,000 patient years).

105. Crucially, these figures were based on the assumption that Antares's revelation of a single suicide event was accurate. It was not. In fact, the recent, publicly-available FDA file and a knowledgeable Company insider confirm that ***multiple suicide events***, as opposed to one, occurred. In the case of the Xyosted NDA, the FDA did distinguish between completed or unsuccessful suicide attempts, and included the one successful and one unsuccessful attempt present in Xyosted's development as "suicide attempts" or simply "suicides."

106. No TRT approved within the last decade recorded a case of completed suicide in the treatment arm of any phase's trial. Xyosted therefore, posed, at minimum, a quantitatively unique safety signal.

107. As the *Healthonym* article noted following Antares's receipt of the CRL:

> Here's the relevant data on this point; the same kind of data the FDA has required of sponsors in the past.
>
> > A. 0.67% of individuals completed suicide in Xyosted's pivotal trial (1 case; n = 150). If we include the phase 3 safety extension study, this comes out to be 0.35% of participants (n = 283); and 0.27% among all available trial data with results (n = 377). Given publicly available information, this is around 447 cases of suicide per 100,000 patient years.
> >
> > B. 0.00% of 1,999 participants in the pivotal trials used to approve 6 TRTs in the past decade completed suicide. Moreover, even suicide ideation and behavior was practically non-existent.
> >
> > C. As before, after extending our data to include another 5 European clinical trials and 7 post-marketing studies, 0.02% of participants completed suicide (1 case; n = 5536). An adequate approximation of completed suicides per 100,000 patient years cannot be gleaned from this set of publicly available data.
> >
> > D. Most men in Xyosted's pivotal trial were 41-66 years old, White, Black, Hispanic, and Asian; observed mainly in 2015. Applying the same criteria to the U.S. population at large, we come to find that 0.03% of all such men in 2015 completed suicide (14,961 cases; n = 51,530,467). This equates to, in a manner of speaking, 29 suicides per 100,000 "patient years".
> >
> > While D establishes only an approximate comparison given trial exclusion/inclusion criteria, the FDA tends to look at this type of information even if only to get a very general understanding of trends.
>
> Therefore, we can clearly see that **the risk of suicide among the general population (0.03%) closely mirrors that of overall TRT trial data (0.02%), while the risk in either is far smaller than that of Xyosted's (0.27%).** (Emphasis in original.)

The *Healthonym* article also mined The FDA Adverse Event Reporting System (FAERS) for the following comparative data:

> A. FAERS data tells us that suicides constituted 0.74% of all deaths correlated to any/all TRTs out on the market (5 suicides; 676 deaths).
>
> > Suicides comprised 0.04% of adverse event cases (5 suicides; 14,816 adverse event cases).

> B. Data from the pivotal, extension, and post-marketing studies on TRTs approved in the past 10 years reveals that suicides constituted 12.5% of all deaths (1 suicide; 8 deaths).
>
> > 0.05% of all adversely affected individuals (n = 2,012) completed suicide. Of note: this latter percentage (0.05%) appears to be consistent with approximately equivalent FAERS data (0.04%).
>
> C. Available phase 1, 2, and 3 data (n = 377) from Xyosted's trials show us 100% of deaths were as a result of suicide (1 suicide; 1 death).
>
> > 0.46% of individuals experiencing an adverse effect (n = 218) completed suicide.
>
> In summation, what most of this data tends to show is that suicide (quantitatively speaking) poses a serious and unprecedented safety signal for Xyosted with respect to its drug class.
>
> It appears that, **among individuals with adverse events, the risk of suicide is roughly 10 times greater for Xyosted than for any other TRT currently in use.** (Emphasis in original.)

108. Defendants reported two cases of depression in what the FDA described as a rather small safety database. The FDA's Division of Pharmacovigilance remarked that most cases of completed suicide described underlying depression and anxiety. Antares itself also cited the link between depression and suicide in communications with the FDA regarding the completed suicide.

Confidential Witnesses

109. Confidential Witness 1 ("CW1") was the Senior Vice President of Pharmaceutical Development with Antares from November 2013 until January 2017. Based at the Company's headquarters in Ewing, New Jersey, CW1 reported directly to Antares's CEO. Most recently, CW1 reported to the Company's current CEO, Defendant Apple.

110. CW1 – a Ph.D. in Pharmaceutics from the University of Utah, Salt Lake City – began at Antares in November 2013 after working at Advantar Laboratories as the Executive Vice President and Chief Operating Officer.

111. At Antares, CW1 was responsible for about eight staff members in New Jersey and then twenty-five employees in the Company's Minneapolis, Minnesota office. Device design for products like the auto-injector that was used to administer testosterone was based in Minnesota.

112. Around six months into CW1's tenure with Antares, CW1 was asked to oversee quality assurance and quality control for pharmaceutical development.

113. CW1 oversaw the non-clinical aspect of developing Antares's future product pipeline.

114. Among other things, CW1's team would also evaluate the characteristics of a new drug's active ingredient to see if there was anything obvious that would show the drug to be ineffective.

115. In addition, CW1 would conduct pre-clinical drug evaluations which consisted of testing the drug in animals.

116. CW1's team was responsible for producing the clinical trial materials for the Xyosted study.

Xyosted Clinical Trial Oversight

117. The product concept for Xyosted was already in progress when CW1 joined the Company, meaning Antares had a preliminary formulation they wanted to move forward with.

118. Antares's Vice President of Clinical and Medical Affairs, Jonathan S. Jaffe ("Jaffe"), oversaw testing for Xyosted. Jaffe reported directly to Defendant Apple. Jaffe was responsible for designing and conducted the studies, monitoring them and making decisions based on data collected from them. He also handled any adverse events that occurred during the course of the studies.

119. According to CW1, an adverse event occurs when someone experiences an adverse effect from taking the drug, such as elevated blood pressure or a heart attack. CW1's understanding of an adverse event is consistent with the FDA's own definition of that term.[8] Whenever an adverse event occurred, the investigator working on the trial would contact Antares.

120. CW2 was the Director of Quality Assurance for Antares from November 2012 to June 2017, based at its Ewing headquarters. CW2 reported directly to Steven Knapp ("Knapp"), the senior vice president of regulatory affairs and quality control/assurance.

121. CW2 attested to the following internal oversight of QST-13-003:

- Everyone at the Company knew about the safety issues with Xyosted because they had to postpone the launch and do an additional safety study (QST-15-005).
- There were only twenty-five (25) to thirty (30) employees at the Ewing headquarters, making it so it would have been impossible for CEO Apple and CFO Powell, not to know about the safety issues that ultimately resulted in boxed warning.
- Medpace, which was conducting the clinical trials of Xyosted for Antares, emailed CW2's team about every issue that came up during the trials.
- There was a dedicated pharmacovigilance group within the Company that monitored adverse effects and they were the ones directly involved with handling these issues. Antares employees on that team included Sally Palmer,

[8] According to FDA regulations, "adverse event" means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.32

Associate Director of Clinical Operations and Project Management and Linda Weiss ("Weiss"), Director of Medical Affairs. Weiss reported directly to Jaffe.

- CEO Apple and CFO Powell were very involved in overseeing the testing and monitoring the progress of Xyosted, CW2 saidit's such a small company -- not like a Johnson & Johnson or Pfizer - people are hands on.

Regular Meetings Were Held Regarding Adverse Events and Clinical Trial Results

122. During 2014 and 2015, staff meetings were held, usually bi-weekly, with the executive team. This included, among others, CW1, Defendant Apple, Defendant Powell, Jaffe, SVP Regulatory Affairs and Quality Assurance Knapp, and the head of pharmacovigilance, Rajesh Thaker.

123. According to CW1, clinical trial results for Xyosted were discussed by the group at these meetings, which were personally moderated by Defendant Apple.

124. CW2 concurred that Defendants Apple and Powell held regular executive management meetings, which Jaffe and Knapp would attend.

125. Although they were not finalized, clinical study reports were presented by Jaffe at meetings held during 2015.

126. At several different staff meetings in 2015, Jaffe reported that some patients in the Xyosted study showed an elevation of blood pressure.

127. CW1 recalled pointing out to meeting attendees the significance of a blood pressure rise of two millimeters in a relatively small study.

128. At the same group meetings early in Xyosted study, there were also updates that multiple suicide events occurred and were being investigated.

129. After Antares began its first Phase 3 study of Xyosted in July 2014, CW2's team had regular weekly meetings at which they'd discuss the various drugs in clinical trials, including Xyosted. In addition, they received regular emails from Medpace, the clinical research organization (CRO) that was administering the clinical trials.

130. CW2 said that when Company employees started hearing about Phase 3 clinical trial-patients having elevated blood pressure, committing suicide, and exacerbating depression, they discussed those issues at the regular, weekly meetings.

131. CW1 stated that when the Xyosted study was finalized, meaning it was checked and confirmed, the high blood pressure and suicide events were confirmed as real observations.

132. CW2 noted that Antares management was upset about the loss of life, such that for the second, six-month study (QST-15-005), monitoring devices for blood pressure were used so if someone tested high, they were not allowed into the study, and questions about depression included in the questionnaire to exclude anyone with a history of depression.

133. CW1 explained that Defendant Jacob, Antares's COB, was very concerned about how it would be viewed by the FDA; at this point, the Company scrambled to do an extension study, *i.e.*, QST-15-005, which formally began in July 2015.

Materially False and Misleading Statements Issued During the Class Period

134. The Class Period begins on December 21, 2016, when Antares announced the Company's submission of its NDA for QST to the FDA. In a press release entitled "Antares Pharma Announces Submission of New Drug Application for QuickShot Testosterone," Defendant Apple claimed, in part, that "the study data demonstrated that the QuickShot auto injector can provide patients with physiologically normal and steady levels of testosterone over the course of therapy." Defendant Apple further claimed that another "benefit to patients is a

virtually painless treatment experience as demonstrated by the pain data collected in our phase 3 program. We will work closely with the FDA during the regulatory review process towards a potential approval with the goal of bringing this new treatment option to men diagnosed with hypogonadism."

135. The price of Antares shares increased upon the announcement of the QST NDA.

136. The statements referenced in ¶134 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the clinical data did not substantiate "physiologically normal" outcomes or "a virtually painless treatment experience" where it established that the clinical studies included one case of completed suicide, one case of suicide attempt, and two cases of depression, as well as a clear tendency towards a high risk of hypertension (12.7% in the pivotal trial); (ii) accordingly, Antares had overstated the approval prospects for Xyosted; and (iii) as a result of the foregoing, Antares' public statements regarding Xyosted were materially false and misleading during the Class Period.

137. On February 27, 2017, Antares issued a press release entitled "Antares Pharma Announces FDA Acceptance of New Drug Application for QuickShot Testosterone," in which it was disclosed that "The FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of October 20, 2017, ten months from the official NDA submission. The PDUFA dates is the target date for the FDA to complete its review of the NDA." The Company further stated that "[t]he study data also showed patients had a virtually painless treatment experience using the device. We will work closely with the FDA during the regulatory review process toward a potential approval."

138. In the press release, Defendant Apple again discussed the alleged "physiologically normal" benefits of Xyosted, as well as stating, in part, that "[w]e continue to believe QST could be an excellent treatment option for men with hypogonadism based upon ***the positive pharmacokinetic and safety data*** produced in the two phase three studies now on file with the FDA." (Emphasis added).

139. The statements referenced in ¶¶137-138 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the clinical data did not substantiate "physiologically normal" outcomes or "a virtually painless treatment experience" where it established that the clinical studies included one case of completed suicide, one case of suicide attempt, and two cases of depression, as well as a clear tendency towards a high risk of hypertension (12.7% in the pivotal trial); (ii) accordingly, it was misleading for the Company to cite "positive … safety data produced in the two phase three studies now on file with the FDA."; (iii), Antares had overstated the approval prospects for Xyosted; and (iv) as a result of the foregoing, Antares' public statements regarding Xyosted were materially false and misleading during the Class Period.

140. On March 14, 2017, Antares filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the quarter and year ended December 31, 2016 (the "2016 10-K"). In the 2016 10-K, Antares stated, with respect to QST-13-003, that:

> The most common adverse reactions ***(incidence ≥5%)*** in this phase 3 study were increased hematocrit, ***hypertension***, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising and headache. ***Serious adverse events (SAE's) reported included one case each of worsening***

depression, vertigo ***and suicide.***

141. The 2016 10-K contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Apple and Powell, stating that the financial information contained in the 2016 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

142. The 2016 10-K was also signed by Defendant Jacob.

143. The statements referenced in ¶¶140-142 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Xyosted's clinical trials showed a clear tendency towards a high risk of hypertension (12.7% in the pivotal trial); (ii) Xyosted's pivotal trial showed a hypertension rate more than ***200% higher*** than clinical trials in comparable, approved TRTs, a fact obscured by Defendants' burying hypertension rates in a randomly-sorted list of adverse effects at a generic "greater than or equal to than five percent" rate; (iii) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (iv) an additional suicide attempt (characterized by the FDA as a "suicide") had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (v) the QST clinical studies included ***two*** cases of depression, not one; (vi) accordingly, Antares had overstated the approval prospects for Xyosted; (vii) Defendants' SOX certifications were false; and (viii) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

144. On April 3, 2017, Antares issued a press release entitled "Antares Pharma Announces Poster Presentation of QuickShot Testosterone Data at the Endocrine Society Annual

Meeting." The press release spoke of Xyosted's "potential approval" and claimed, in part, that "QST was found to be ***safe***, well tolerated and virtually pain free" (Emphasis added). The press release further stated that:

> The most common adverse reactions ***(incidence ≥5%)*** in the phase 3 study referenced in these presentations were increased hematocrit, ***hypertension***, increased PsA, Upper Respiratory Tract Infection, sinusitis, injection site bruising and headache. ***Serious adverse events reported included one case each of worsening depression***, vertigo ***and suicide.***

145. The statements referenced in ¶144 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the clinical data did not substantiate Defendants' claimed safety outcomes where it established that the clinical studies included a clear tendency towards a high risk of hypertension (12.7% in the pivotal trial) as well as one case of completed suicide, one case of suicide attempt, and two cases of depression; (ii) Xyosted's clinical trials showed a clear tendency towards a high risk of hypertension (12.7% in the pivotal trial); (iii) Xyosted's pivotal trial showed a hypertension rate more than ***200% higher*** than clinical trials in comparable, approved TRTs, a fact obscured by Defendants' burying hypertension rates in a randomly-sorted list of adverse effects at a generic "greater than or equal to five percent" rate; (iv) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (v) an additional suicide attempt (sometimes characterized by the FDA as a "suicide") had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (vi) the QST clinical studies included ***two*** cases of depression, not one (vii) accordingly, Antares had overstated the approval prospects for Xyosted; and (viii) as a result of the foregoing, Antares's public statements regarding Xyosted

were materially false and misleading during the Class Period.

146. Also on May 9, 2017, Antares held its First Quarter 2017 Operating and Financial Results Conference Call ("Q1 2017 Conference Call"). On the Q1 2017 Conference Call, Defendant Apple claimed, in response to an analyst question, that "nothing unusual" had occurred with respect to the FDA review of Xyosted.

147. The statements referenced in ¶146 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Xyosted's "product profile" – which included a clear tendency towards a high risk of hypertension (12.7% in the pivotal trial), as well as one case of completed suicide, one case of suicide attempt, and two cases of depression – was inconsistent with Defendants' claims regarding prospective market share capture; (ii) Defendants could not reasonably claim that "nothing unusual" had occurred with respect to the FDA review of Xyosted when Defendants had been told by the FDA in late 2016 that hypertension, suicide, and depression would be review issues, that the adverse events might impact labeling, and that an advisory committee might be needed; (iii) Antares had overstated the approval prospects for Xyosted; and (iv) as a result of the foregoing, Antares' public statements regarding Xyosted were materially false and misleading during the Class Period.

148. The same day, Antares filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended March 31, 2017 (the "Q1 2017 10-Q"). In the Q1 2017 10-Q, Antares stated, in part:

> The most common adverse reactions ***(incidence ≥5%)*** in this phase 3 study were increased hematocrit, ***hypertension***, increased prostate-specific antigen, upper

> respiratory tract infection, sinusitis, injection site bruising and headache. ***Serious adverse events (SAE's) reported included one case each of worsening depression,*** vertigo ***and suicide***.

149. The Q1 2017 10-Q contained signed certifications pursuant to SOX by Defendants Apple and Powell, stating that the financial information contained in the Q1 2017 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

150. The statements referenced in ¶¶148-149 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension (12.7% in the pivotal trial); (ii) Xyosted's pivotal trial showed a hypertension rate more than ***200% higher*** than clinical trials in comparable, approved TRTs, a fact obscured by Defendants' burying hypertension rates in a randomly-sorted list of adverse effects at a generic "equal to or greater than five percent" rate; (iii) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (iv) an additional suicide attempt (characterized by the FDA as a "suicide") had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (v) the QST clinical studies included ***two*** cases of depression, not one; (vi) accordingly, Antares had overstated the approval prospects for Xyosted; (vii) Defendants' SOX certifications were false; and (viii) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

151. On August 8, 2017, Antares held its Second Quarter 2017 Operating and Financial Results Conference Call ("Q2 2017 Conference Call"). During the Q2 2016

Conference Call, Defendant Apple stated that "…. anyone who is diagnosed with testosterone deficiency, we believe, is the perfect candidate for XYOSTED."

152. Defendant Apple further stated that "I think that there isn't any particular patient population that has testosterone deficiency that we're excluding or that we think is a better candidate."

153. The statements referenced in ¶¶151-152 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Xyosted's clinical study demonstrated that patients suffering from hypertension, depression, and suicidal ideation were objectively less suitable Xyosted patients, in that their survival was potentially compromised by using Xyosted; (ii) Defendants had themselves excluded patients with high blood pressure from QST-15-005; and (iii) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

154. Also on August 8, 2017, Antares filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended June 30, 2017 (the "Q2 2017 10-Q"). In the Q2 2017 10-Q, Antares stated, in part:

> The most common adverse reactions ***(incidence ≥5%)*** in this phase 3 study were increased hematocrit, ***hypertension***, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising and headache. ***Serious adverse events (SAE's) reported included one case each of worsening depression,*** vertigo ***and suicide***.

155. The Q2 2017 10-Q contained signed certifications pursuant to SOX by Defendants Apple and Powell, stating that the financial information contained in the Q2 2017

10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

156. The statements referenced in ¶¶154-155 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Xyosted's pivotal trial showed a clear tendency towards a high risk of hypertension (12.7%); (ii) Xyosted's pivotal trial showed a hypertension rate more than ***200% higher*** than clinical trials in comparable, approved TRTs, a fact obscured by Defendants' burying hypertension rates in a randomly-sorted list of adverse effects at a generic "greater than or equal to than five percent" rate; (iii) the risk of suicide with Xyosted was far greater than with any other currently marketed TRT; (iv) an additional suicide attempt (characterized by the FDA as a "suicide") had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (v) QST-13-003 had included two cases of depression, not one; (vi) accordingly, Antares had overstated the approval prospects for Xyosted; (vii) Defendants' SOX certifications were false; and (viii) as a result of the foregoing, Antares's public statements regarding Xyosted were materially false and misleading during the Class Period.

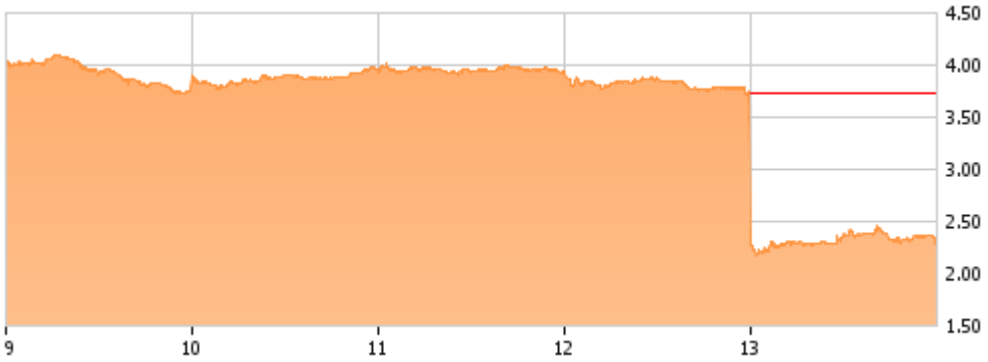
The Truth Emerges

157. On October 12, 2017, after the market had closed, Antares issued a press release entitled "Antares Pharma Provides Xyosted Regulatory Update." In the press release, Antares stated, in part:

> EWING, NJ, October 12, 2017 -- Antares Pharma, Inc. (NASDAQ: ATRS) today announced that, on October 11, 2017, the Company received a letter from the U.S. Food and Drug Administration (FDA) stating that, as part of their ongoing review of the Company's New Drug Application (NDA) for XYOSTED™ (testosterone

> enanthate) injection, they have identified deficiencies that preclude the continuation of the discussion of labeling and postmarketing requirements/commitments at this time. The letter does not specify the deficiencies identified by the FDA and there has been no further clarification of the deficiencies by the FDA at this time. We anticipate receiving further clarification from the FDA on or before the Prescription Drug User Fee Act (PDUFA) date of October 20, 2017. The Company intends to work with the FDA to understand the nature of the deficiencies once identified and resolve them as quickly as possible.
>
> On December 20, 2016, the Company submitted to the U.S. Food and Drug Administration a New Drug Application pursuant to section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FDCA), for testosterone enanthate subcutaneous injection. On February 24, 2017, the Company received a letter from the FDA notifying the Company that the FDA assigned a PDUFA target date for completion of its review by October 20, 2017. On September 22, 2017, the Company received labeling comments from the FDA which the Company responded to on September 29, 2017.

158. On this news, the Company's share price fell $1.41, or 37.80%, to close at $2.32 on October 13, 2017, as illustrated below:



159. On October 20, 2017, following the following the end of the Class Period, Antares issued a press release entitled "Antares Pharma Receives Complete Response Letter From the FDA for XYOSTED." The press release stated, in part:

> EWING, N.J., Oct. 20, 2017 (GLOBE NEWSWIRE) -- Antares Pharma, Inc. (ATRS) announced that today it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for XYOSTED™ (testosterone enanthate) injection. ***The CRL indicates that the FDA cannot approve the NDA in its present form.***

> ***The CRL identified two deficiencies related to clinical data***. Based on findings in studies QST-13-003 and QST-15-005, the FDA is concerned that XYOSTED™ could cause a ***clinically meaningful increase in blood pressure***. In addition, the letter also raised a concern regarding the occurrence of ***depression and suicidality***. The CRL did not cite any Chemistry, Manufacturing and Controls (CMC), device or efficacy issues with regard to XYOSTED™. The next step will be to request a meeting with the FDA to further evaluate the deficiencies raised and to agree upon a path forward for a potential approval of XYOSTED™.
>
> "We are disappointed with the outcome of the review and are assessing the content of the Complete Response Letter, including the information that may be needed to resolve the deficiencies," said Robert F. Apple, President and Chief Executive Officer. "The Company remains committed to bringing XYOSTED to market and will work closely with the FDA to determine the appropriate responses to the deficiencies noted in the letter." (Emphasis added.)

160. The CRL stated, in pertinent part:

> 1. Based on the findings in Studies QST13-003 and QST15-005, ***we are concerned that your testosterone enanthate product could cause a clinically meaningful increase in blood pressure*** … We are concerned that these unexpected findings based on data from a largely normotensive population may underestimate the effects of your drug on blood pressure in the real world setting, where many patients have co-existing hypertension, with the potential to increase the risk for adverse cardiovascular outcomes.
>
> 2. ***There were two cases of suicide attempt*** (including one completed suicide) and ***two cases of depression*** in your development program….

161. On the same day the CRL issued, the FDA's Deputy Director of Division of Bone, Reproductive and Urologic Products filed an internal memo quoting the Cross-Discipline Team Leader (CDTL) and reviewer as follows:[9]

> A clinically meaningful increase in blood pressure (BP) was observed in normotensive hypogonadal male patients after 12 weeks of treatment with QuickShot testosterone enanthate (QST TE) in the phase 3 study QST 15-005. Results from ambulatory blood pressure monitoring (ABPM) assessments

[9] According to the FDA, the CDTL provides day-to-day management of the review, performs a secondary review of the overall application taking into account all discipline reviews and recommendations, and maintains consistency of regulatory decisions and direction of the review. *See* https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=cder&id=CDER-OCP-Number-of-Cross-Discipline-Reviews-Led-by-OCP

> conducted in that safety study demonstrated group mean increases in systolic and diastolic BP (SBP and DBP) of approximately 4 mmHg and 2 mmHg, respectively. In addition, cumulative distribution function (CDF) curves generated from these ABPM data demonstrated that approximately 60% of all patients in the study incurred an increase in SBP of up to 20 mmHg. ***Further, 9.5% of patients in the study required initiation or adjustment of antihypertensive medications in order to maintain BP in the normal range.*** The observation of increased BP related to treatment with QST TE was also observed in the pivotal phase 3 study QST 13-003. ***This observed increase in BP, coupled with the deficiencies in the design of QST-005, constitutes a major Clinical deficiency for this NDA, and for this reason predominantly, the Clinical review team recommends a Complete Response action be taken for this NDA***. (Emphasis added.)

162. The FDA Clinical Reports also cited the effect of Antares' regulatory shortcut on the rejection: "neither Phase 3 study included a concurrent control or blinding methodology; thus, the independent effect of QST TE on [blood pressure] may be even larger than reported to date."

163. From October 12, 2017 through November 8, 2017, Antares common stock declined from a high of $4.09 per share to a low of $1.58 per share.

164. On December 12, 2017, Antares first posted study results for QST-13-003 online, and admitted that the initial rate of hypertension for the study was 15.2%, or nearly four times the rate in comparable, approved TRTs.

165. Subsequently, on January 11, 2018, Antares revised this figure downward to 12.7%.

166. On April 5, 2018, Antares announced that the FDA had acknowledged receipt of the Company's March 29, 2018 resubmission to the CRL received in connection with the Xyosted NDA. The FDA considered this resubmission a complete response and assigned a PDUFA of September 29, 2018.

167. On October 1, 2018, Antares announced that it had received FDA approval for Xyosted, but required a black box warning addressing the FDA's concerns cited back in October

2017:

- **XYOSTED™ can cause blood pressure increases that can increase the risk for major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death, with greater risk for MACE in patients with cardiovascular risk factors or established cardiovascular disease.**
- **Before initiating XYOSTED™, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled.**
- **Starting approximately 6 weeks after initiating therapy, periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension in patients on XYOSTED™.**
- **Re-evaluate whether the benefits of XYOSTED™ outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease while on treatment.**
- **Due to this risk, use XYOSTED™ only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.**

168. The approval also required a separate section under "WARNINGS AND PRECAUTIONS" to address the risk of depression and suicide associated with Xyosted revealed in October 2017:

> **Risk of Depression and Suicide—**Depression and suicidal ideation and behavior, including completed suicide, have occurred during clinical trials in patients treated with XYOSTED™. Advise patients and caregivers to seek medical attention for manifestations of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes.

169. As a further condition of approval, Antares agreed to provide a separate report concerning depression and suicide case reports in each quarterly NDA Periodic Adverse Event Report (PADER) for the first three years of Xyosted marketing.

170. The pharma industry blog *FiercePharma* cautioned that "Antares can start touting its once-weekly drug's ease of use—Xyosted is an at-home self-injection, while AndroGel is a daily rub-on product—but will also have to contend with a black-box warning detailing risks of blood pressure increases that can lead to serious cardiovascular problems."[10]

171. Black box warnings are the strictest labeling requirements that the FDA can

[10] https://www.fiercepharma.com/pharma/aiming-for-abbvie-s-androgel-antares-scores-fda-nod-for-testosterone-drug-xyosted

mandate for prescription drugs. First implemented in 1979, black box warnings highlight serious and sometimes life-threatening adverse drug reactions within the labeling of prescription drug products.

172. Investor resource site *The Motley Fool* explains that –

> The Food and Drug Administration gives "black box" warnings to prescription drugs with side effects that can lead to serious injury or death. Officially termed a "boxed warning" by the agency, they're displayed in the upper left of the full prescribing information section of the drug's label.
>
> Drugs with such a label are banned from what the FDA considers "reminder ads" -- the type that display the name of the drug but don't include a list of side effects. Advertising limitations are just one effect a black-box warning can have on a drug's commercial potential.
>
> For some indications, black-box warnings can severely limit a new drug's chances of a successful commercial launch. For example, MannKind's Afrezza began with a black-box warning that required physicians to perform a detailed medical history, physical examination, and lung-strength test before prescribing the inhalable insulin product. With plenty of available options for diabetics that don't require jumping through these hoops, Afrezza's initial launch was a flop.[11]

173. The black box warning for Xyosted is of particular concern because the Company took on debt to finance the development of the drug (*see* ¶94 above) and because, as a writer on *Seeking Alpha* noted, "[t]he company has never turned a profit, and until recently, has never even had a substantial product revenue stream."[12]

174. As a direct result of the black box and suicide warnings, the price of Antares stock – trading 6.4 million shares – ranged from a high of $3.64 (near the open) to a low of $3.21 (nearly a 12% swing), closing the day near the low at $3.26, a 3% drop from the previous day's close of $3.36:

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[11] *See* https://www.fool.com/knowledge-center/what-does-it-mean-for-a-drug-label-to-have-a-black.aspx

[12] *See* https://seekingalpha.com/article/4111040-antares-numerous-upcoming-catalysts

175. Between March and June 2019, Antares shares fell following the approval of Clarus Therapeutics' oral TRT drug Jatenzo, which does has not been deemed a depression/suicide risk by the FDA.

176. On May 2, 2019, Antares issued a press release announcing a net loss of $5.5 million (or $0.03 per share) for the first quarter of 2019 ("Q1 2019"). While the Company's operating expenses increased due to additional sales and marketing expenses associated with the launch of Xyosted, Antares disclosed that its Q1 2019 increase in product revenue was primarily driven by sales of auto injector devices for use with Teva's generic epinephrine product, and not Xyosted.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

177. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Antares securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures and/or materialization of the risks. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

178. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Antares securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Antares or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

179. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

180. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

181. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the

questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Antares;
- whether the Individual Defendants caused Antares to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Antares securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

182. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

183. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Antares securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Antares securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

184. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

185. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

186. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

187. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

188. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances

under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Antares securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Antares securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

189. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Antares securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Antares's finances and business prospects.

190. By virtue of their positions at Antares, and as evidenced by their primary roles in communicating with investors about Antares's finances and business prospects, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the

truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

191. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Antares, the Individual Defendants had knowledge of the details of Antares's internal affairs. In addition, Defendant Jacob's suspiciously-timed sale of 230,000 shares of Antares stock for a profit of $931,920 demonstrates his awareness of the Company's inner workings.

192. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Antares. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Antares's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Antares securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Antares's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Antares securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

193. During the Class Period, Antares securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and

misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Antares securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Antares securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Antares securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

194. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

195. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure and/or materialization of the risk that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

196. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

197. During the Class Period, the Individual Defendants participated in the operation

and management of Antares, and conducted and participated, directly and indirectly, in the conduct of Antares's business affairs. Because of their senior positions, they knew the adverse non-public information about Antares's misstatement of income and expenses and false financial statements.

198. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Antares's financial condition and results of operations, and to correct promptly any public statements issued by Antares which had become materially false or misleading.

199. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Antares disseminated in the marketplace during the Class Period concerning Antares's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Antares to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Antares within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Antares securities.

200. Each of the Individual Defendants, therefore, acted as a controlling person of Antares. By reason of their senior management positions and/or being directors of Antares, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Antares to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Antares and possessed the power to control the specific activities which comprise the primary violations about which

Plaintiff and the other members of the Class complain.

201. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Antares.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

LITE DEPALMA GREENBERG, LLC

Dated: May 29, 2020

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